DEPARTMENT OF HEALTH & HUMAN SERVICES

5164

CERTIFIED MAIL
RETRUN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2001-DT-10

February 9, 2001

Leighton Lum, D.O.
Medical Director, Mammography
Medical Diagnostic Imaging
5980 South Main Street
Clarkston, MI 48346

Dear Dr. Lum:

We are writing you because on February 6, 2001, your facility was inspected by a representative of the State of Michigan acting in behalf of the Food & Drug Administration (FDA). The inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed the following Repeat Level 2 finding at your facility:

1. [redacted] of [redacted] random medial reports reviewed did not contain an assessment category as required by 21 CFR Part 900.12 (c)(1)(iv). The referenced reports contained a final assessment of "Deferred", which is not defined by the regulations.

The specific problems noted above appeared on your MQSA Facility Inspection Report (copy enclosed), which was issued at the close of the inspection. These problems are identified as Repeat Level 2 because it identifies a failure to meet a significant MQSA requirement, and it indicates a failure by your facility to implement permanent correction of problems found during your previous inspection. Specifically, this same violation was reported during your previous inspection of February 28, 2000. A response to that finding was received from Mr. John E. Kibble, MA, ATC Director, on April 21, 2000 with assurances that this violation had been corrected.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to placing your facility under a Directed Plan of Correction, charging your facility for the cost of onsite monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that is also listed on the inspection report provided to facility personnel at the conclusion of the inspection. This Level 2 finding is:

1. Corrective action before further exams, for a failing image score, or a phantom background optical density or density difference outside the allowable regulatory limit was not taken for the [redacted] unit in room 1.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- the specific steps you have taken to correct the Repeat Level 2 and Level 2 violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to: Mr. David M. Kaszubski
Director Compliance Branch
U. S. Food & Drug Administration
1560 East Jefferson Ave.
Detroit, MI 48207-3179

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's.

Finally, you should understand that there are many FDA requirements pertaining

to mammography. This letter only pertains to findings of your inspection and does not necessarily address other obligations you have under law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have any questions regarding this letter or how to ensure that you are meeting MQSA standards, please call Mr. Dennis E. Swartz, Radiological Health Expert, at 313-226-6260 Ext. 155.

Sincerely yours,

John P. Dempster

for Raymond V. Mlecko
District Director
Detroit District

Enclosures: a/s